REMARKS

The present communication responds to the Office action of February 28, 2008, which the Examiner made final and in which the Examiner rejected claims 1-6, 8, 9, 12, 13, 17 and 19. The drawings and claims 6, 9, 12 and 13 were objected to for informalities. Claim 13 was rejected under 35 U.S.C. § 112. Claims 1-5, 17 and 19 were rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Patent 4,444,560 ("Jacklich"). Claims 6, 9 and 12 were rejected under 35 U.S.C. § 102(e) as anticipated by U.S. Patent 6,575,939 ("Brunel"). Claim 13 was rejected under 35 U.S.C. § 102(e) as anticipated by U.S. Patent Publication 2003/0144632 ("Hommann et al."). Claim 8 was rejected under 35 U.S.C. § 103(a) as unpatentable over Jacklich in view of U.S. Patent 4,850,967 ("Cosmai").

Claims 1, 6, 13 and 17 have been amended. No new subject matter has been added to the claims. Support for amended claims 1, 6, 13 and 17 can be found in general throughout the specification and in particular, for example, at page 12, lines 1-6, page 17, lines 21-28, and FIGS. 1 and 6.

The claim rejections are traversed in view of the amendments and for at least the reasons articulated below.

Reconsideration is requested.

Drawings

The drawings were objected to under 37 C.F.R. § 1.83(a), but the Examiner also indicated that the objection could be overcome by amending the specification to indicate that the releasing element is a radial projection (50). This has been done and, therefore, withdrawal of the objection is requested.

Specification

In the specification, paragraph [0045] has been amended and recites *inter alia* that, "[t]he activating member 17 may include a radial projection, which also may be thought of and referred to as a releasing element 50 extending through an opening 52 in the housing 23, 24."

Claim Objections

Claims 6, 9, 12 and 13 were objected to for informalities.

Claims 6 and 13 have been amended to recite "the fluid product" instead of "said fluid product" thereby obviating the objection to the claims. Claims 9 and 12 depend directly or indirectly from amended claim 6, and the amendment to claim 6 obviates the objection to the dependent claims.

Reconsideration and withdrawal of the objection to claims 6, 9, 12 and 13 are requested.

Rejection under 35 U.S.C. § 112

Claim 13 was rejected under 35 U.S.C. § 112, second paragraph.

Reconsideration and withdrawal of the rejection are requested because the claim has been amended to recite "a product container for fluid product" thereby providing a positive recitation of the product container.

Rejections under 35 U.S.C. § 102

Jacklich

Claims 1-5, 17 and 19 were rejected under 35 U.S.C. § 102(b) as anticipated by Jacklich.

This rejection is traversed for at least the following reasons.

Amended claim 1 is directed to an injection device for administering a fluid product comprising, in part, an "operating means for operating said piston rod... said operating means formed as a one-piece lever comprising a lever arm and a protrusion, the protrusion projected substantially perpendicular from the lever arm towards a longitudinal axis of the injection device."

Jacklich discloses a compact anesthetic syringe. As can be seen with reference to FIGS. 1 and 2, the syringe includes an operating handle 53 coupled to a ratchet 57, which is a separate pivotal piece. The separate ratchet 57 is pivoted on the handle 53 and a spring 55 biases the

ratchet 57 into a groove 49. (*Jacklich, col. 2, lines 23 – 27*). The syringe also includes a piston rod 61 having a number of ratchet teeth 63. (*Jacklich, col. 2, lines 28 – 30*). In operation, as the handle 53 is worked back and forth, the piston rod 61 will advance into the cylinder. (*Jacklich, col. 2, lines 35 – 37*). As can be seen with reference to FIGS. 1 and 2, such advancement is achieved by the separate ratchet 57, extending at an acute angle from the operating handle 53, engaging the ratchet teeth 63 of the piston rod 61. Also, as can be appreciated by reference to FIGS. 1 and 2, advancement of the piston rod 61 could not occur if the ratchet 57 extended from the operating handle 53 at any angle other than an acute angle. Specifically, advancement of the piston rod 61 could not occur if the ratchet 57 extended substantially perpendicular from the operating handle 53.

Jacklich does not disclose an "operating means formed as a one-piece lever comprising a lever arm and a protrusion, the protrusion projected substantially perpendicular from the lever arm towards a longitudinal axis of the injection device," as recited in amended claim 1.

Claims 2-5 depend directly from claim 1 and are patentable over Jacklich for at least those reasons set forth above with respect to amended claim 1.

Amended claim 17 is directed to an injection device comprising, in part, "operating means pivotable in a radial direction relative to the device about a fulcrum arranged laterally on the device, wherein the operating means includes a one-piece lever comprising a lever arm and a protrusion . . . and a releasing element for releasing a dosage amount to be dispensed by the injection device, wherein the releasing element projects through an opening in the casing of the injection device, and dimensions of the opening limit movement of the releasing element, thereby determining the dosage amount to be dispensed, wherein the dosage amount is released by moving the releasing element from a first stopper on a first side of the opening to a second stopper on a second side of the opening, opposite the first side."

As discussed above regarding amended claim 1, Jacklich does not disclose an "operating means pivotable in a radial direction relative to the device about a fulcrum arranged laterally on the device, wherein the operating means includes a one-piece lever comprising a lever arm and a protrusion," as recited in amended claim 17.

Furthermore, Jacklich does not disclose the invention of claim 17 because it does not disclose that "the dosage amount is released by moving the releasing element from a first stopper on a first side of the opening to a second stopper on a second side of the opening, opposite the first side."

The Examiner asserts that the device of Jacklich discloses "a protrusion (65)" and "a releasing element (57) for releasing a dosage amount." (*Office Action, page 6*). As discussed above, and with reference to FIGS. 1 and 2, Jacklich discloses a ratchet 57 which extends through an opening in the casing 9 and engages the piston rod 61. Previously, the ratchet 57 was likened to Applicant's protrusion. (*Office Action, page 5*). However, in amended claim 17 the releasing element and the protrusion are both recited elements. Neither a ratchet 57 nor a pawl 65 of Jacklich could be characterised as the protrusion of amended claim 17.

Assuming, for purposes of argument, that the ratchet 57 of the device of Jacklich could be properly characterized as a releasing element, the Examiner has failed to identify a first stopper on a first side of the opening and a second stopper on a second side of the opening. Applicants respectfully assert that Jacklich does not disclose such elements. As can be seen with reference to FIG. 2, at most, the ratchet 57 may be moved to a first stopper 49 on a side of the opening. At no time during operation of the device does the ratchet 57 contact any other portion of the casing 9.

Accordingly, Jacklich does not disclose that "the dosage amount is released by moving the releasing element from a first stopper on a first side of the opening to a second stopper on a second side of the opening, opposite the first side," as recited in amended claim 17.

Claim 19 depends directly from claim 17 and is patentable over Jacklich for at least those reasons set forth above with respect to amended claim 17.

Reconsideration and withdrawal of the § 102 rejection of claims 1-5, 17 and 19 are requested.

Brunel

Claims 6, 9 and 12 were rejected under 35 U.S.C. § 102(e) as anticipated by Brunel.

Amended claim 6 is directed to an injection device for administering a fluid product comprising, in part, "dosing means for releasing a predetermined amount of a dosage . . . wherein said dosing means comprises a releasing element for releasing the dosage, wherein the releasing element projects radially outward and extends through an opening in the casing of the injection device, and dimensions of said opening limit movement of the releasing element, thereby setting the predetermined amount of the dosage, wherein the predetermined amount of the dosage is released by moving the releasing element from a first stopper on a first side of the opening to a second stopper on a second side of the opening, opposite the first side."

Brunel discloses a device for automatically injecting a dose of a medicinal product. The device includes a sleeve 12 provided with a trigger 15 in its peripheral wall. (*Brunel, col. 6, lines 1-4*). The trigger 15 has a longitudinal bar 15a oriented in the direction of the rear end of the sleeve 12 and is adapted so that when pressed by a finger, the transverse member 15b retracts inside the sleeve. (*Brunel, col. 6, lines 5-10*). The sleeve 12 may be situated in a retracted position (FIG. 14) in which actuation of the trigger 15 is prevented, or in a forward position (FIG. 15) in which actuation of the trigger 15 is enabled. (*Brunel, col. 8, lines 35 – 63*). Injection of the medicinal product is obtained by actuating the trigger 15 which leads to a deformation of a tongue 39 and freeing of a stirrup 35, which in turn, initiates a cascade of events culminating in injection and complete emptying of the product. (*Brunel, col. 8, line 64 to col. 9, line 10*).

The trigger 15 does not project radially outward and extends through an opening of the device of Brunel, but rather, is formed integrally on the sleeve 12 in a longitudinal direction. The trigger 15 has a corrugated upper face provided with transverse ribs such as 16 projecting with respect to the peripheral wall of the sleeve 12. (*Brunel, col. 6, lines 10-12 and FIGS. 1 and 2*). However, these ribs 16 do not project radially outward, and extend through an opening in the

casing of the injection device. The ribs merely give corrugation to the upper face of the trigger 15. Therefore, there is a structural difference between Brunel and amended claim 6.

Claims 9 and 12 depend directly or indirectly from claim 6 and are patentable over Brunel for at least those reasons set forth above with respect to amended claim 6.

Reconsideration and withdrawal of the § 102 rejection of claims 6, 9 and 12 are requested.

Hommann et al.

Claim 13 was rejected under 35 U.S.C. § 102(e) as anticipated by Hommann et al.

Claim 13 has been amended to recite "a product container for fluid product" thereby providing a positive recitation of the product container.

Hommann discloses an injection device. The device 10 substantially consists of three parts: first, a casing 12; second, an ampoule 14 having an injection needle 16 and a discharge piston 18; and third, a needle protecting sleeve 20. (*Hommann et al., page 2, paragraph 31*). The ampoule 14 is held by the casing such that the ampoule 14 together with the injection needle 16 and piston 18 can be removed from the casing and disposed of. (*Hommann et al., page 3, paragraph 49*). However, Hommann et al. does not disclose a holder for the ampoule, therefore there is no disclosure of "a casing, a product container for fluid product, a holder for the product container of the fluid product, an injection needle, and a needle protector, wherein the needle protector comprises a sleeve ," as recited in amended claim 13. Therefore, there is a structural difference between Hommann et al. and amended claim 13.

Reconsideration and withdrawal of the § 102 rejection of claim 13 are requested.

Rejection under 35 U.S.C. § 103

Claim 8 was rejected under 35 U.S.C. § 103(a) as unpatentable over Jacklich in view of Cosmai.

This rejection is traversed because claim 8 depends indirectly from amended claim 1 and is directed to the injection device of claims 1 and 5, wherein the "indicator comprises a scale up to a total number of dosage amounts contained in the product container and counts down by one unit on the scale when the piston rod or the operating means is operated."

As discussed above, Jacklich does not disclose the invention of amended claim 1 at least because it does not disclose an "operating means formed as a one-piece lever comprising a lever arm and a protrusion, the protrusion projected substantially perpendicular from the lever arm towards a longitudinal axis of the injection device."

Cosmai fails to remedy the fundamental disclosure deficiencies of Jacklich, as neither Cosmai nor Jacklich discloses or suggests the features of amended claim 1.

Applicant requests, therefore, that the rejection of claim 8 under § 103(a) over Jacklich in view of Cosmai be withdrawn.

Conclusion

This response is being submitted on or before July 28, 2008, with the required fee for a two-month extension of time, making this a timely response. It is believed that no additional fees are due in connection with this filing. However, the Commissioner is authorized to charge any additional fees, including extension fees or other relief which may be required, or credit any overpayment and notify us of same, to Deposit Account No. 04-1420.

The application now stands in allowable form, and reconsideration and allowance are respectfully requested.

Respectfully submitted,

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